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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,322	10/18/2007	David R. Milich	643802000203	3500

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,322	MILICH ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *170-172,174-178 and 188-197* is/are pending in the application.

4a) Of the above claim(s) *175-178,189,191,193-195 and 197* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *170-172,174,188,190,192 and 196* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/18/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: full-text of Paoletti reference.

DETAILED ACTION

1. Claims 170-172, 174-178, and 188-197 are pending in the application.

Election/Restrictions

2. Applicant's election of Group I, and the species wherein the hepadnavirus core antigen is from a rodent, esp. a ground squirrel in the reply filed on October 30, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 175-178, 189, 191, 193-195, and 197 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 30, 2008.

4. Claims 170-172, 174, 188, 190, 192, and 196 are under consideration.

Priority

5. Applicant is requested to update the status of the parent US applications identified in the priority statement on page 1 of the application to indicate that they have been issued as US patents 7,320,795 (from application 10/630070), and 7,144,712 (from application 10/630074).

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on October 18, 2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

7. No date has been provided for reference 125 of the IDS as required by 37 CFR 1.98(b)(5). The reference has therefore not been considered.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 170-172 rejected under 35 U.S.C. 102(b) as being anticipated by Paoletti et al. (Vaccine 20:370-76- of record in the October 2007 IDS). It is noted that the reference was first published online in October 2001. See attached copy of full-text of the article from publisher website (top of 2nd page of printout). These claims are drawn to methods for the production of an immune response comprising administering to an animal a hybrid particle comprising a non-primate hepadnavirus core antigen and a heterologous antigen such that the particle generates an immune response (esp. an antibody or IgG antibody immune response) to the heterologous antigen.

Paoletti teaches a method for inducing an immune response to a target antigen comprising the administration of a duck hepatitis B (a hepadnavirus) core antigen coupled with a heterologous antigen (a streptococcal antigen). Abstract, page 371-72. The reference also teaches that the coupled core antigen/heterologous antigen particles induced the production of IgG antibodies against the heterologous antigen. See e.g., page 374, Table 3. The reference therefore anticipates the indicated claims.

10. Claims 170-172, 174, 190, 192, and 196 are rejected under 35 U.S.C. 102(a) as being anticipated by Birkett et al. (U.S. 2003/0054337- of record in the October 2007 IDS). Claims 170-172 have been described above. Claims 174, 190, and 192 are directed more particularly to embodiments wherein the core antigen is from a rodent, esp. a ground squirrel, hepadnavirus. Claim 196 requires that the C-terminal portion of the core protein is replaced by 1-100 amino acids that are not (a) a single cysteine residue or (b) the wild-type sequence of the core particle.

Birkett teaches HBc particles for the delivery of a heterologous epitope. The reference indicates that the HBc particles may be derived from the core particles of HBV, or of other related hepadnaviruses such as the core antigen of the grounds squirrel hepatitis virus. Page 3, paragraph [0034]. The reference also indicates that the C-terminal end of the protein may be truncated, and replaced with sequences of up to 100 amino acids in length. See e.g., pages 7-8, and claim 1. The reference therefore anticipates the indicated claims.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claim 188 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti et al. (supra). This claim is directed to the claimed methods, wherein the subject to whom the compositions is administered is a human with pre-existing antibodies to HBV core antigen. As indicated above, the reference teaches the administration of a conjugate of a non-primate (i.e. a duck) hepadnavirus core antigen and a heterologous antigen to an animal to induce an immune response against the heterologous antigen. The reference does not actually disclose the administration of the conjugate to a human as described by claim 188. However, the reference teaches that the duck hepadnaviral core protein does not react with antibodies directed to human HBV. Page 371, left column. Based on this, the reference suggests the use of the duck virus core protein as a carrier for foreign antigens for use in humans as it would not be expected that pre-existing HBcAg antibodies would influence the immunogenicity of the duck virus core based compositions. The teachings of the reference therefore render the claimed invention obvious.

13. Claims 170-172, 174, 188, 190, 192, and 196 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birkett et al. (supra) in view of the teachings of Paoletti et al. (supra) and of Maruyama et al. (Gastroenterol 106:1006-15) and Shödel et al. (Vaccine 11:624-28- of record in the October 2007 IDS). Claims 170-172, 174, 190, 192, and 196 have been described

previously, as have the teachings of Birkett which render these claims obvious (i.e. anticipated). Claim 188 has also been described above.

Birkett teaches the use of the disclosed hybrid HBc particles for delivery of the included foreign antigen to humans. See e.g., pages 7 (paragraph [0085]) and 17 (paragraph [0199]). However, the reference is silent as to the specific use of non-primate hepadnaviral core particles for the induction of immune responses in humans with pre-existing anti-HBV antibodies as required by claim 188.

As was described above, Paoletti suggests the use of the duck hepatitis core antigen for use an antigen carrier for delivery of the antigens to humans due to the lack of cross-reactivity between antibodies to the HBV core antigen and the duck core antigen. Page 371. Other teachings in the art indicate that there is a similar low cross-reactivity of antibodies between the human HBV core antigen and the core antigens of rodent hepatitis viruses. See e.g., Maruyama, page 1011 (right column); and Shödel, abstract, pages 626 (first sentence of section "immunization and protection") and 627 (middle of right column- indicating that the dominant B-cell epitopes of HBcAg appear not to be conserved in WHcAg). It would therefore have been obvious to those of ordinary skill in the art to use the rodent hepatitis core antigens as carriers for the antigens as taught by Birkett for use in inducing an immune response in the humans identified in claim 188. This is because they would have had a similar expectation that such rodent core particles would also benefit from the low cross-reactivity in the same manner as suggested by Paoletti with respect to the duck core particles.

The teachings of the cited references therefore render the claimed method obvious.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 170-172, and 174 re rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 14-28 of U.S. Patent No. 7,320,795. Although the conflicting claims are not identical, they are not patentably distinct from each other

because the claims of the present application are drawn to methods of using the composition described by the patented claims. See, Pfizer Inc. v. Teva Pharmaceuticals USA Inc., 86 USPQ2d 1001, at 1007-1008 (indicating the protection from double patenting afforded by 35 USC §121 does not apply to CIP applications, and that there is no patentable distinction between a composition and method of using such that is disclosed by the application claiming the composition). The present application is not a divisional of the patent, or a divisional of a parent or child of the application from which it was issued.

17. Claim 188 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 14-28 of U.S. Patent No. 7,320,795 in view of the teachings of Paoletti et al. (supra) and of Maruyama et al. (Gastroenterol 106:1006-15) and Shödel et al. (Vaccine 11:624-28- of record in the October 2007 IDS). As indicated above, this claim limits the claimed method to embodiments wherein the subject to whom the compositions is administered is a human with pre-existing antibodies to HBV core antigen. Such is not disclosed by the claims or the specification of the patent. However, as described above, the teachings of Paoletti suggest the use of non-HBV hepadnaviral core antigens with no reactivity to anti-HBV core antigen as carriers for antigens for use in humans to avoid problems associated with pre-existing antibodies against the HBV core antigen. Each of Maruyama and Shödel teach that the core antigen from at least the Woodchuck rodent hepadnavirus also has low reactivity with antibodies to the HBV core antigen. See, Maruyama, page 1011 (right column); and Shödel, abstract, pages 626 (first sentence of section “immunization and protection") and 627 (middle of right column- indicating that the dominant B-cell epitopes of HBcAg appear not to be conserved

in WHcAg). It would therefore have been obvious to those of ordinary skill in the art that the use of rodent hepatitis core particles would be equally (or nearly) as useful as the duck core antigens of Paoletti for delivery of foreign antigens to humans. Thus, it would have been obvious to those of ordinary skill in the art to administer the compositions of the patent claims to the humans identified in claim 188. The present claim is therefore not patentably distinct from the patented claims.

18. Claims 170-172, 174, 192, and 196 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32, 36-44, 47-64 of copending Application No. 12/008059. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are drawn to methods of using the composition described by the copending application. See, Pfizer Inc. v. Teva Pharmaceuticals USA Inc., 86 USPQ2d 1001, at 1007-1008 (indicating the protection from double patenting afforded by 35 USC §121 does not apply to CIP applications, and that there is no patentable distinction between a composition and method of using such that is disclosed by the application claiming the composition). It is noted that the present application is not a divisional of the copending application, or a divisional of a parent or child of that application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claim 188 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32, 36-44, 47-64 of copending Application No. 12/008059, further in view of Paoletti et al. (supra), Maruyama et al. (supra), and Shödel et al. (supra). This rejection is on substantially the same basis as asserted above with respect to the rejection of claim 188 over the claims of U.S. Patent No. 7,320,795 in view of the same secondary references.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

20. No claims are allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648